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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,570	09/15/2003	Luc R. Mongeon	1023-203US01	2842

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,570	MONGEON ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,10,12-26 and 28-45* is/are pending in the application.

4a) Of the above claim(s) *43-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,10,12-26 and 28-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 10, 12-26, and 28-42 are rejected under 35 U.S.C. 102(b) as anticipated by Soykan et al. (US 6,151,525, hereinafter "Soykan") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Soykan in view of Heil, Jr. et al. (US 4,819,662, hereinafter "Heil").

5. In regards to claims 1, 21, and 35, Soykan discloses a method/system comprising a lead for delivering electrical stimulation to tissue (col. 13, line 38) and eluting genetic material from a polymeric matrix (col. 11, line 1) to cause transgenic expression that increases the conductivity at the stimulation site. Increasing the contractile ability of the stimulation area (from cells that do not contract at all, per column 1, lines 57-58, to cells that contract, per the abstract of the disclosure) inherently increases the conductivity because non-contractile cells do not have the membrane proteins that allow for cell contraction, while contractile cells do have these proteins. This inherent and fundamental feature of these cells means that the conductivity is increased in the region of these new cells. Further, because the matrix is "incorporated in" the carrier, the matrix is inherently in a chamber body. Alternatively, Heil teaches of providing a lead with a chamber for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's invention by providing a lead with a chamber to provide the predictable result of providing controlled release of agents at the site of electrical therapy.

6. In regards to claims 2 and 22, Soykan discloses that the matrix is extracellular collagen (col. 11, line 47).

7. In regards to claims 4, 23 and 37, the matrix is cross-linked (col. 11, line 55). The level of cross-linking is inherently proportional to the release rate.

8. In regards to claims 10 and 26, the delivery vector is a liposome (claim 7).

9. In regards to claims 16 and 17, a genetic material and dexamethasone are delivered (col. 11, line 35).

10. In regards to claims 18 and 32, the electrode is implantable (col. 13, line 49).

11. In regards to claims 19 and 33, the tissue is cardiac tissue (abstract).

12. In regards to claims 20 and 34, because the method is providing contractile tissue between the stimulator and healthy tissue, the method creates a preferential conduction pathway between the stimulation site and intrinsic conduction system.

13. Claims 3, 12-15, 28-31, 36, and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan (or Soykan in view of Heil). Soykan (or Soykan in view of Heil) discloses the essential features of the claimed invention, including using autologous biological material (col. 5, line 67) that is incorporated just prior to delivery by swelling the hydrogel (col. 11, line 59), but does not disclose a freeze-dried (lyophilized) or frozen matrix, a genetic material causing expression of connexin or IkB, a genetic material that causes expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent, placing the matrix in the lead just before implantation, or soaking of the distal end of the lead in the genetic material. It is well

known in the art to freeze-dry or freeze matrix to increase the shelf-life of the biologically active substance, to provide a genetic material causing expression of connexin or IkB to improve the conductive quality of cardiac tissue, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to reduce rejection complications in a host patient, and to soak (or swell) matrix in genetic material before placement into the body (either before delivery, or right at delivery) to allow autologous biological substances to be implanted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's (or Soykan in view of Heil's) invention by freeze-drying or freezing matrix to provide the predictable result of increasing the shelf-life of the biologically active substance, providing a genetic material causing expression of connexin or IkB to provide the predictable result of improving the conductive quality of cardiac tissue, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to provide the predictable result of reducing rejection complications in a host patient and soaking matrix in genetic material before placement into the body to provide the predictable result of allowing autologous biological substances to be implanted.

14. Claims 9, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Heil. Soykan discloses the essential features of the claimed invention except for eluting the material via a porous electrode, or a chamber body that is separable from the lead body. Heil teaches of providing an implantable lead with a porous electrode (32) to provide controlled elution of an agent placed in a chamber

within the lead, and a chamber body that is separable from the lead body (Fig. 7) to allow loading of the agent at the time of implantation (col. 6, line 60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Soykan's invention with a porous electrode to provide the predictable result of providing controlled elution of an agent placed in a chamber within the lead, and a chamber body that is separable from the lead body to provide the predictable result of allowing loading of the agent at the time of implantation.

Response to Arguments

15. Applicant's arguments filed 6/28/2007 have been fully considered but they are not persuasive. Applicant argued that Soykan is lacking disclosure of increasing the conductivity of tissue at the stimulation site. Please see the grounds for rejection elaborated above, and further see Peters et al. (US 2005/0119704), paragraph 0062 as evidence that fibroblasts are non-conductive. As the converted myocytes of Soykan's invention are conductively stimulated by the electrode device, this is an inherent disclosure of increasing the conductivity of the tissue.

16. Applicant's arguments with respect to claims 14 and 30 have been considered but are moot in view of the new ground(s) of rejection, necessitated by the amendment of claims 1 and 21.

17. Applicant further argued that Soykan is lacking disclosure of providing a preferential conduction pathway between the stimulation site and intrinsic conduction system. Because the conduction properties of the tissue are altered (as explained

above), some arbitrary "preferential" conduction pathway is created because there exists some "preferential" path of least resistance.

18. Applicant further argued that Examiner's assertion of well-known knowledge in the art was improper because no references were cited to support such assertion. However, evidence to support the Examiner's assertion was provided in the last Office Action in paragraph 19, as well as the "Notice of References Cited" document. For Applicant's convenience, the references are again cited below.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nabel et al. (US 5,328,470) is one of many teachings of assembling a biological material administration kit just before delivery and freeze-drying matrix; Girouard et al. (US 2004/0158289) is one of many teachings of administering connexin-43; Palasis et al. (US 6,749,617) is one of many teachings of providing IkB to cardiac tissue; and March et al. (US 5,797,870) is one of many teachings of providing gene therapy that causes expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEORGE R. EVANIS
PRIMARY EXAMIN
6/23/7

MWK
8/21/07